DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT 19 1990

Ms. Joanne H. Ogilvie
Director
Amuchina USA
2 Wisconsin Circle, Suite 706
Chevy Chase, Maryland 20815

Re: K885037
Amukin 50% - Airspray(R)
Dated: November 29, 1988
Received: December 5, 1988
Regulatory Class: II

Dear Ms. Ogilivie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968 such as the requirement to submit an initial report prior to marketing radiation emitting devices, or other applicable Federal laws or regulations.

This letter immediately will allow you to begin marketing your device if you have met all other requirements described above. An FDA finding of substantial equivalence of your device to a pre-Amendment device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Halyna P. Breslawec, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

The following information is herein being submitted in conformance with 21 CFR 20.29:

1. Classification Name: None
   Common/Usual Name: Disinfectant for connector sites used in dialysis
   Trade/Proprietary Name: Amuchina 50% Airspray®

2. Establishment Registration Number: The establishment registration number for Amuchina Soc.p.Az. is 8021034.

3. Classification: Amuchina 50% Airspray® has not been classified by the FDA. The chemical composition of Amuchina 50% Airspray® is being submitted as Exhibit A.

4. Performance Standards: No performance standards applicable to the disinfection of connector sites used in dialysis have been established by the FDA.

5. A draft label is enclosed as Exhibit B.

6. Using Amuchina 50% Airspray on connector sites in dialysis is substantially equivalent to using povidone iodine on connector sites. The equivalency of Amuchina 50% Airspray on connector sites in dialysis is supported by the following:

   Exhibit C: Determination of the Sporicidal Effectiveness of Two Sporicidal Products;

   Exhibit D: Effectiveness of AMUKIN-50% in a "Y"-Set for CAPD Treatment (with Attachments No. 1-11);

   Exhibit E: Safety of AMUKIN-50% in a "Y"-Set for CAPD Treatment (with Attachment No. 12).

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Section Content Menu Skip to Common Links

510(k) Premarket Notification

510 (k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search Back To Search Results

Device Classification Name	Set, Administration, For Peritoneal Dialysis, Disposable
510(K) Number	K871583
Device Name	MODIFIED LABELING FOR AMUKIN-50%
Applicant	AMUCHINA INTL., INC. 12120a Heritage Park Circle Silver Spring, MD 20906
Contact	Cooney, Pa
Regulation Number	876.5630
Classification Product Code	KDJ
Date Received	04/23/1987
Decision Date	07/09/1987
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Gastroenterology/Urology
Review Advisory Committee	Gastroenterology/Urology
Type	Traditional
Reviewed By Third Party	No
Expedited Review	

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Section Content Menu Skip to Common Links

510(k) Premarket Notification

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search Back To Search Results

Device Classification Name	System, Peritoneal, Automatic Delivery
510(K) Number	K862928
Device Name	AMUKIN-50% FOR CAPD Y-SET
Applicant	AMUCHINA INTL., INC. 12120a Heritage Park Circle Silver Spring, MD 20906
Contact	Bernard J Cooney
Regulation Number	876.5630
Classification Product Code	FKX
Date Received	08/01/1986
Decision Date	03/09/1987
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Gastroenterology/Urology
Review Advisory Committee	Gastroenterology/Urology
Type	Traditional
Reviewed By Third Party	No
Expedited Review	